ARC 4903C

PHARMACY BOARD[657]

Adopted and Filed

Rule making related to expedited partner therapy

The Board of Pharmacy hereby amends Chapter 6, "General Pharmacy Practice," Chapter 7, "Hospital Pharmacy Practice," Chapter 8, "Universal Practice Standards," and Chapter 18, "Centralized Prescription Filling and Processing," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 147.76.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 139A.41.

Purpose and Summary

The amendments allow a pharmacist to fill a non-patient-specific prescription when the prescription is issued pursuant to Iowa Code section 139A.41 for the purpose of expedited partner therapy to treat a sexually transmitted chlamydia or gonorrhea infection in an unnamed partner or partners.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on October 9, 2019, as **ARC 4693C**. The Board received two comments from the public, both in support of the amendments with no suggested changes. No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Board on January 8, 2020.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on March 18, 2020.

The following rule-making actions are adopted:

ITEM 1. Amend subrule 6.10(1) as follows:

6.10(1) *Required information.* The label affixed to or on the dispensing container of any prescription drug or device dispensed by a pharmacy pursuant to a prescription drug order shall bear the following:

a. and *b.* No change.

c. ~~Except~~ The name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner, except as provided in 657—subrule 8.19(7) for epinephrine auto-injectors, ~~or~~ 657—subrule 8.19(8) for opioid antagonists, ~~the name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner;~~ or 657—subrule 8.19(9) for expedited partner therapy.

d. to *g.* No change.

h. The initials or other unique identification of the dispensing pharmacist, unless the identification of the pharmacist involved in each step of the prescription filling process is electronically documented and retrievable.

ITEM 2. Adopt the following **new** subrule 6.13(4):

6.13(4) *Expedited partner therapy.* When a pharmacy dispenses a prescription drug pursuant to Iowa Code section 139A.41 and 657—subrule 8.19(9) for expedited partner therapy, a pharmacy is only required to maintain the information about the patient who is known to the pharmacy.

ITEM 3. Amend rule 657—7.12(124,126,155A) as follows:

657—7.12(124,126,155A) Drugs in the emergency department. Drugs maintained in the emergency department are kept for use by or at the direction of prescribers in the emergency department. Drugs shall be administered or dispensed only to emergency department patients. For the purposes of this rule, "emergency department patient" means a patient who is examined and evaluated in the emergency department and includes the partner or partners of a patient treated pursuant to Iowa Code section 139A.41.

7.12(1) and **7.12(2)** No change.

7.12(3) *Drug dispensing.* Only a pharmacist or prescriber may dispense any drugs to an emergency department patient pursuant to the provisions of this rule.

a. No change.

b. Prescriber responsibility. Except as provided in subrule 7.12(4), a prescriber who authorizes the dispensing of a prescription drug to an emergency department patient is responsible for the accuracy of the dispensed drug and for the accurate completion of label information pursuant to this paragraph, including when any portion of the dispensing process is delegated to a licensed nurse under the supervision of the prescriber.

(1) Except as provided in subrule 7.12(4), at the time of delivery of the drug the prescriber shall be responsible for ensuring that the dispensing container bears a label with at least the following information:

1. Name and address of the hospital;
2. Date dispensed;
3. Name of prescriber;
4. Name of patient, except when the drug is dispensed for one or more unnamed partners receiving expedited partner therapy pursuant to Iowa Code section 139A.41;
5. Directions for use; and
6. Name, quantity, and strength of drug.

(2) No change.

7.12(4) No change.

ITEM 4. Amend paragraph **8.19(1)"a"** as follows:

a. Written, electronic, or facsimile prescription. In addition to the electronic prescription application and pharmacy prescription application requirements of this rule, a written, electronic, or facsimile prescription shall include:

(1) No change.

(2) The name and address of the patient except as provided in subrule 8.19(7) for epinephrine auto-injectors, ~~and in~~ subrule 8.19(8) for opioid antagonists, or subrule 8.19(9) for expedited partner therapy.

(3) to (5) No change.

ITEM 5. Adopt the following **new** subrule 8.19(9):

8.19(9) *Expedited partner therapy.* Pursuant to Iowa Code section 139A.41, a physician, physician assistant, or advanced registered nurse practitioner may issue a prescription to one or more sexual partners of an infected patient for an oral antibiotic intended to treat a sexually transmitted chlamydia or gonorrhea infection. The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall not be required to contain the patient name and address. The prescription shall indicate the antibiotic is being issued for the purpose of expedited partner therapy. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

ITEM 6. Amend rule 657—8.21(155A) as follows:

657—8.21(155A) Prospective drug use review.

8.21(1) For purposes of promoting therapeutic appropriateness and ensuring rational drug therapy, a pharmacist shall review the patient record, information obtained from the patient, and each prescription drug or medication order to identify:

~~1.~~ *a.* Overutilization or underutilization;
~~2.~~ *b.* Therapeutic duplication;
~~3.~~ *c.* Drug-disease contraindications;
~~4.~~ *d.* Drug-drug interactions;
~~5.~~ *e.* Incorrect drug dosage or duration of drug treatment;
~~6.~~ *f.* Drug-allergy interactions;
~~7.~~ *g.* Clinical abuse/misuse;
~~8.~~ *h.* Drug-prescriber contraindications.

Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem and shall, if necessary, include consultation with the prescriber. The review and assessment of patient records shall not be delegated to pharmacy technicians or pharmacy support persons but may be delegated to registered pharmacist-interns under the direct supervision of the pharmacist.

8.21(2) A pharmacist shall be exempt from the requirements of subrule 8.21(1) when dispensing a prescription issued to an unnamed patient for an oral antibiotic pursuant to Iowa Code section 139A.41.

ITEM 7. Amend subrule 18.3(4) as follows:

18.3(4) *Central fill label requirements.* The label affixed to the prescription container filled by a central fill pharmacy on behalf of an originating pharmacy shall include the following:

a. to *c.* No change.

d. ~~Except~~ The name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner, except as provided in 657—subrule 8.19(7) for epinephrine auto-injectors, ~~or~~ 657—subrule 8.19(8) for opioid antagonists, ~~the name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner;~~ or 657—subrule 8.19(9) for expedited partner therapy.

e. to *h.* No change.

i. The initials or other unique identification of the pharmacist who performed drug use review, unless the identification of the pharmacist involved in each step of the prescription filling process is electronically documented and retrievable.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 2/12/20.